

Official Title: Does the Use of Liposomal Bupivacaine Decrease Narcotic Requirements in Geriatric Hip Fractures? A Randomized, Double Blinded Control Trial

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Statistical Analysis Plan for Randomized Controlled Trial for Exparel Hip Fracture (H00013594)

Primary Outcome Variables: Total morphine equivalents in the post-operative period for 24, 48, and 72 hours, CAM score and average Pain Visual Analog Scale

Secondary Outcome Variables: Length of stay, discharge disposition, timing and participation with inpatient physical therapy, complications and 30 day readmission.

Comparisons between continuous variables will be made using Students t-test, and categorical variables using the Chi-square statistic or Fischer's Exact Test, based on incidence.

Power analysis: Recent studies evaluating regional nerve blocks in hip fractures have shown an average morphine sulfate equivalent of 3.5 +/- 0.52 mg/d in the first 3 postoperative days. That same study showed a 33% reduction in morphine equivalents (3.5 mg/d vs 2.1 mg/d). Assuming a similar effect size, this study would require only 8 patients group to be powered to 80% with a significance level of 0.05. With a target recruitment goal of 50 patients, the study would be powered to detect differences as low as 0.42 mg/d (a 12% effect size)